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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,712	12/06/2001	John Walter Liebeschuetz	00111/US1	3427
24330	7590	01/14/2004	EXAMINER	
Martin A. Hay 13 Queen Victoria Street Macclesfield Cheshire UK, SK11 6LP UNITED KINGDOM			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,712	Applicant(s) LIEBESCHUETZ ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-10,12,16-21,23,27-29,32,34-39 and 41-43 is/are pending in the application.
4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,6,8-10,12,19-21,23,27-29,32,34-39 and 41-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on Nov. 7, 2003, the applicants have elected group XIV with traverse for further prosecution in response to restriction requirement. The applicants have also canceled claims 2-5, 7, 11, 13-15, 22, 24-26, 30, 31, 33 and 40, amended claims 1, 6, 8, 10, 12, 23, 29, 32, 34, 36 and 38 and furthermore, have added new claims 42 and 43. Claims 16-18 are withdrawn from further consideration as being directed to non-elected inventions.

2. Claims 1, 6, 8-10, 12, 19-21, 23, 27-29, 32, 34-39 and 41-43 are now pending in the application.

Response to Arguments

3. Applicant's arguments filed on Nov. 7, 2003 regarding restriction requirement have been fully considered but they are not persuasive. The examiner does not agree with the applicants arguments that the applicants did not sought protection for some groups mentioned in the restriction requirement. All the groups defined in the restriction requirement were based on the values of variables R2, X, Y, Cy, L and Lp claimed in claim 1. Based on the values of these variables in the original claim 1, there was no common core present and furthermore, covered millions of compounds and therefore, it was not even possible to start searching these compounds. Thus, restriction requirement as indicated is proper and thereby made final.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 6, 8-10, 12, 19-21, 23, 27-29, 32, 34-39 and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claims 1 and 29, the value of variable R1a is defined. However, this variable is not present in these amended claims. An appropriate correction is required.

Also, the term ---A serine protease inhibitor compound--- is indefinite since it is not clear whether this inhibition occurs in vitro or in vivo and furthermore, the steps for achieving this inhibition are missing.

Claims 6 and 32 are vague because the intent is not clear. Since variable Y in the amended claims 1 and 29 can only be -CH. The applicants need to clarify this.

Claims 34 and 35 depend directly or indirectly upon claim 33 which has been canceled. An appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 6, 8-10, 12, 19-21, 23, 27-29, 32, 34-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki (U.S. Patent no. 5,182,284).

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Suzuki discloses piperazine compounds, pharmaceutical compositions containing these compounds and a method of treating various diseases using these compounds. The compounds 21 and 22 (see columns 38 and 39) disclosed by Suzuki anticipate the instant claims when R2 and Cy represent phenyl group and Lp represents piperazine group in the instant compounds of formula (I). It is of note that inhibition of serine protease will be inherent since Suzuki teaches therapeutic utility of these compounds.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 6, 8-10, 12, 19-21, 23, 27-29, 32, 34-39 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong (U.S. Patent no. 6,339,087).

Gong discloses cyclic amine derivatives, pharmaceutical compositions containing these compounds and a method treating various diseases using these compounds. The compounds no. 22, 34 and 35 (see columns 11-12) disclosed by Gong differ from the instant compounds in having the value of variable L as -CH₂ instead of -(CH₂)₂ (when R₂ and Cy represent phenyl group, L represents (CH₂)_{m+2} and m is 0 and Lp represents piperazine in the instant compounds of formula (I)) since they differ by only -CH₂ group. However, the compounds of Gong are structural homologs of the instant compounds and the structural homologs are well known in the art to have the same utility.

10. Claims 1, 6, 8-10, 12, 19-21, 23, 27-29, 32, 34-39 and 41-43 are objected as containing non-elected subject matter. The applicants are suggested to amend the claims to delete non-elected subject matter since the restriction is made final.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (703)305-4482. The examiner can normally be reached on Monday through Thursday, 7:30 A.M. to 6:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625